APPENDIX A.

Opinion of the United States Court of Appeals, For the Second Circuit.

(Filed April 13, 1966.)

THE TOILET GOODS ASSOCIATION, INC.; ANITA D'FOGED, INC.; AVON PRODUCTS, INC.; BEAUTY COUNSELORS, INC.; BONNE BELL, INC.; BOURJOIS, INC.; CHARLES OF THE RITZ, INC.; CHESEBROUGH-POND'S INC.; CHRISTIAN DIOR PERFUMES CORP.; CLAIROL INCORPORATED; COLONIAL DAMES CO., LTD.; COTY, INC.; FABERGE INC.; FRANCES DENNY, INC.; THE FULLER BRUSH CO.; THE GEORGE W. LUFT CO., INC.; THE GILLETTE COMPANY; A. M. HANSEN, doing business as HOUSE OF HOLLYWOOD; HARPER METHOD, INC.; HELENA RUBINSTEIN, INC.; HELENE CURTIS INDUSTRIES, INC.; HENRY/HARAN/HUTCHINGS, INC.; HERBOLD LABORATORY, INC.; JOHN H. BRECK, INC.; KOLMAR LABORATORIES, INC.; LADY LENNOX COMPANY, INC.; LEHN & FINK PRODUCTS CORPORATION; ARNOLD L. LEWIS, doing business as STUDIO COSMETIC CO.; MAX FACTOR & CO.; MAYBELLINE CO.; MERLE NORMAN COSMETICS, INC.; JACK B. NETHERCUTT, doing business as NETHERCUTT LABORATORIES; NEUTROGENA CORP.; NUTRILITE PRODUCTS, INC.; OLD 97 COMPANY; PRIVATE LABEL COSMETICS CO., INC.; PURITAN COSMETICS CO.; REVLON, INC.; ROUX LABORATORIES, INC.; SHULTON, INC.; and YARDLEY OF LONDON, INC.,

Plaintiffs-Appellees,

v.

JOHN W. GARDNER, Secretary of Health, Education and Welfare, and JAMES L. GODDARD, Commissioner of Food and Drugs,

Defendants-Appellants.

Before:

WATERMAN, MOORE and FRIENDLY,

Circuit Judges.

Appendix A.

Appeal by the Secretary of Health, Education and Welfare and the Commissioner of Food and Drugs from an order of the District Court for the Southern District of New York, Harold R. Tyler, Jr., *Judge,* denying their motion to dismiss or grant summary judgment in an action for a declaration of invalidity of four Food and Drug Administration regulations relating to color additives. Affirmed as to Counts 1, 2 and 3; reversed as to Count 4.

ARTHUR S. OLICK (Robert M. Morgenthau, United States Attorney for the Southern District of New York; James G. Greilsheimer, Assistant United States Attorney, of Counsel), *for Defendants-Appellants.*

EDWARD J. ROSS (Breed, Abbott & Morgan, New York, N. Y.; Stephen R. Lang, of Counsel), *for Plaintiffs-Appellees.*

FRIENDLY, Circuit Judge:

In July 1960, Congress added to the Federal Food, Drug, and Cosmetic Act a number of new provisions known as the Color Additive Amendments, 74 Stat. 397, 21 U. S. C. §§321-376. These were intended

> "to authorize the use of suitable color additives in or on foods, drugs, and cosmetics in accordance with regulations to be issued by the Secretary of Health, Education, and Welfare, prescribing the conditions, including maximum tolerance, under which such additives may be safely used." H. R. Rep. No. 1761, 86th Cong., 2d Sess., 1960 U. S. Code Cong. & Ad. News 2887.

The Commissioner of Food and Drugs, to whom the Secretary of Health, Education and Welfare has delegated the Department's functions under the Act, 22 F. R. 1051 (1957),

25 F. R. 8625 (1960), held rule-making proceedings conforming to §4 of the Administrative Procedure Act, 5 U. S. C. §1003, and issued Color Additive Regulations, 21 C. F. R. Part 8, effective, with certain exceptions, on June 22, 1963.

The following November the Toilet Goods Association, a trade organization of cosmetic manufacturers whose members allegedly represent 90% of annual United States sales, and forty manufacturers and distributors of cosmetics brought this action against the Secretary and the Commissioner in the District Court for the Southern District of New York for a declaratory judgment that four provisions of the Regulations exceeded the authority conferred by the statute. Jurisdiction was properly predicated on 28 U. S. C. §§1331 and 1337. See *Smith* v. *Kansas City Title & Trust Co.*, 255 U. S. 180 (1921).[1] The defendants moved to dismiss or to strike certain portions of the complaint on various grounds, among others that the case was inappropriate for declaratory relief and that the action was an unconsented suit against the sovereign; plaintiffs cross-moved for summary judgment. In November 1964 Judge Tyler denied both motions in an opinion, 235 F. Supp. 648, relying in part on *Abbott Labs.* v. *Celebrezze*, 228 F. Sup. 855 (D. Del. 1964), where the court had granted a declaratory judgment invalidating labeling regulations under the same statute. A year later, when the case was nearly ready for trial, the Secretary and the Commissioner renewed their

[1] We thus do not reach the question whether §10 of the Administrative Procedure Act, 5 U. S. C. §1009, constitutes an affirmative grant of jurisdiction with respect to the review of federal administrative action, as the Supreme Court apparently assumed in *Rusk* v. *Cort*, 369 U. S. 367, 371-72 (1962) and we recently did in *Cappadora* v. *Celebrezze*, —— F. 2d —— (2 Cir. 1966). But see *Ove Gustavsson Contracting Co.* v. *Floete*, 278 F. 2d 912 (2 Cir.), cert. denied, 364 U. S. 894 (1960). Since 28 U. S. C. §§1336-40 do not require a jurisdictional amount, this question arises only in cases such as social security, passport and citizenship matters, where none of these sections is applicable and the jurisdictional amount required by §1331 is not met.

motion to dismiss on the two grounds stated, arguing that a different conclusion on "the issue of justiciability" was called for by the Third Circuit's reversal of the *Abbott Laboratories* decision, 352 F. 2d 286 (1965),[2] and the District of Columbia Circuit's recent holding that declaratory relief was not available to challenge certain regulations adopted under the Tobacco Inspection Act, 7 U. S. C. §714(b), *Danville Tobacco Ass'n* v. *Freeman*, 351 F. 2d 832 (D. C. Cir. 1965). Judge Tyler adhered to his determination but, at the defendants' request, made the necessary certification for an application to prosecute an interlocutory appeal under 28 U. S. C. §1292(b); permission to appeal was granted by a panel of this court.

I.

The first two counts of the complaint charge that the Regulations exceed the authority conferred by the statute in treating finished cosmetic products and all diluents—unpigmented materials with which colors are mixed—as "color additives" subject to various requirements for testing and administrative certification. The basic section of the Color Additive Amendments is §706 of the Act, 21 U. S. C. §376, which provides that a "color additive" shall be deemed unsafe unless it meets two conditions:[3] The additive must be covered by a "regulation," issued by the Secretary on a finding of suitability, which lists it for use either generally or under prescribed conditions; and it must either come from a batch certified for such use by the Secretary under appropriate regulations or have been exempted from the certification requirement.

The term "color additive," on which the controversy turns, is defined in §201(t)(1), as a material which

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[2] Subsequent to the argument of this appeal, certiorari was granted, 34 U. S. L. Week 3294 (March 1, 1966) (No. 824).

[3] This is subject to an exception, not here important, for color additives covered by an exemption for investigational use by qualified experts, 21 U. S. C. §§376(a)(2) and (f).

> (A) is a dye, pigment, or other substance made by a process of synthesis . . . or otherwise derived . . . from a vegetable, animal, mineral, or other source, and
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> (B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto.
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> 21 U. S. C. §321(t)(1)

The Regulations of the Food and Drug Administration (FDA) interpret the statutory definition of color additive as including "all diluents" and state further that

> A substance that, when applied to the human body results in coloring, is a "color additive," unless the function of coloring is purely incidental to its intended use, such as in the case of deodorants. Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body are "color additives." Reg. §8.1(f).

The term "diluent" is defined as:

> any component of a color additive mixture that is not of itself a color additive and has been intentionally mixed therein to facilitate the use of the mixture in coloring foods, drugs, or cosmetics or in coloring the human body. The diluent may serve another functional purpose in the foods, drugs, or cosmetics, as for example sweetening, flavoring, emulsifying, or stabilizing, or may be a functional component of an article intended for coloring the human body.
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> Reg. §8.1(m)

The manufacturers admit that the coloring ingredient in a cosmetic is a "color additive" fully subject to both

listing and certification requirements of §706, and that a "diluent," in what they insist is the accepted definition of an inert substance used to dilute dyes and pigments, is subject to the Secretary's power to certify additives "with safe diluents or without diluents," §706(c). They complain, however, that the Regulations' comprehensive definition of "color additive" goes beyond the reach of the statute in imposing both listing and certification requirements on finished products—like lipstick, nail polish, etc.—and non-color ingredients that were never intended to be subject to premarketing clearance, and on traditional diluents that were meant to be subject only to certification as components of dyes and pigments.

The third count of the complaint relates to provisions in the Regulations which attempt to subject hair dye products to premarketing clearance in what is alleged to be violation of the exemption recognized in the statute. The Act as passed in 1938, in defining those cosmetics that were deemed to be adulterated, contained in §601(a) an explicit exemption for hair dyes:

> This provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.", and the labeling of which bears adequate directions for such preliminary testing.
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> 52 Stat. 1054

The exemption was carried forward in §601(e) which declared that a cosmetic should be deemed adulterated "If it is not a hair dye and it bears or contains a coal-tar color other than one" from a certified batch. When Congress revised the statute in the 1960 Amendments, it left §601(a) as it was but modified §601(e) to read "If it is not a hair

dye and it is, or it bears or contains, a color additive which is unsafe'' within the meaning of §706.

The Regulations recognized the statutory exemption where proper labeling called for use of the patch test but, armed with an expansive definition of ''color additive'' in §8.1(f) which would on its face seem to include in a preparation for use on the hair any coloring ingredient as well as the finished product, proceeded to limit the exemption as follows:

> The ''hair dye'' exemption in section 601(a) of the act applies to those articles intended for use in altering the color of the hair and which are, or which bear or contain, color additives with the sensitization potential of causing skin irritation in certain individuals and possible blindness when used for dyeing the eyelashes or eyebrows. The exemption is permitted with the condition that the label of any such article bear conspicuously the statutory caution and adequate directions for preliminary patch-testing. If the poisonous or deleterious substance in the ''hair dye'' is one to which the caution is inapplicable and for which patch-testing provides no safeguard, the exemption does not apply; nor does the exemption extend to poisonous or deleterious diluents that may be introduced as wetting agents, hair conditioners, emulsifiers, or other components in a color shampoo, rinse, tint, or similar dual-purpose cosmetics that alter the color of the hair.
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> Reg. §8(u)

The manufacturers claim that the Regulations go beyond the statute in several ways: Whereas the 1938 Act literally exempted from premarketing clearance any coal-tar hair dye complying with the statutory condition of notice and the amendments did not purport to effect any change, the Regulations grant exemption only if the color additive in the hair dye substance is one whose irritating qualities would be detected by a patch test; and, contrary to the

longstanding interpretation—in effect by regulation when the amendments were adopted[4]—which applied the exemption in its full scope to dual-purpose hair products like shampoos, rinses and tints with a coal-tar coloring component, the Regulations seem to limit the exemption to the coloring ingredient itself.

Count 4 of the complaint attacks a section of the Regulations, §8.28(a)(4), which states that when it appears to the Commissioner that a person has refused to permit duly authorized employees of the FDA "free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived," he may suspend certification service to such person until adequate corrective action is taken. The first sentence of §704(a) of the Act, applicable to all goods, drugs, devices, or cosmetics subject thereto, authorizes the Secretary to inspect any "factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials; containers, and labelling therein"; the second sentence, dealing only with places where prescription drugs are manufactured, processed or held, provides for inspection extending "to all things therein (including records, files, papers, processes, controls, and facilities)." The manufacturers say the challenged regulation illegally extends to cosmetics the broadened inspection authorized only for prescription drugs, and improperly subjects trade secrets to exposure.

The expanded definition of "color additives," the narrowing of the hair dye exemption, and the allegedly compelled disclosure of secret formulae and processes impose, the manufacturers claim, burdens not contemplated by the statute and threaten immediate and irreparable injury. Even though coloring ingredients have been properly pre-

[4] Reg. §1.200 apparently defined the term "coal-tar hair dye" in the §601(a) exemption to include "all articles containing any coal-tar color." This definition of hair dyes was deleted by the Commissioner as superseded by §8.1(u) of the Color Additive Regulations. 28 F. R. 10638 (1963).

tested, listed and certified in compliance with the statutory clearance scheme, the regulations require filing a separate listing application for each finished product, traditional diluent and non-color ingredient, including those formerly exempted under the hair dye provision; each application must be accompanied by a $2600 filing fee, Reg. §8.50(c), and supported by extensive scientific tests establishing suitability for intended use, Reg. §8.4(c). Even after listing, every ingredient and finished product must come from a certified batch unless the Secretary has granted an exemption; a minimum fee of $100 is charged for each certification, Reg. §8.51(a). An affidavit by one manufacturer claimed that the listing of its finished products alone for the issuance of regulations would entail filing fees of $7,000,000 and testing costs of nearly $42,000,000, and that certification fees for a single year would amount to $750,000.[5] Beyond such out-of-pocket costs, increased by substantial additional expenses for record-keeping, compliance with the challenged regulations, by requiring significant changes in established business practices and curtailing distribution of new products, allegedly would cause major and costly disruption of the cosmetic industry. Moreover, the disclosure of formulae and processes necessary to meet the new listing requirements and to avoid loss of certification for refusing inspection allegedly would result in misappropriation of trade secrets and discourage research and development of improved cosmetic products.

Failure to comply with the challenged regulations could have serious consequences if they are valid. Under §601 of the Act, a cosmetic other than a hair dye is deemed adulterated if "it is, or it bears or contains, a color additive which is unsafe" within the meaning of §706(a). Projection of any adulterated article into the stream of interstate com-

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[5] Very likely these figures are exaggerated since they take no account either of the FDA's power to require information on diluents as a condition of approving coloring ingredients and granting certification or of the likelihood of exemption from certification.

merce and refusal to allow inspection required by §704 are prohibited acts under the statute, and are subject to injunction and entail criminal liability, §§301-303; and any adulterated article may be seized under §304. The manufacturers say that, apart from all else, the publicity incident to criminal or civil proceedings against them for failure to comply with the Regulations would be seriously detrimental in a highly competitive industry which spends millions in cultivating public good will and is dependent on consumer confidence in the integrity of its products.

The Secretary and the Commissioner respond that the fears as to the dilemma posed by the Regulations are exaggerated. They insist that the Regulations merely expound the manner in which they intend to construe the amendments, that nothing has yet been done to apply the provisions of which plaintiffs complain, and that ample opportunity to test the Regulations in concrete fact situations is afforded by the path for review spelled out in the statute. If the manufacturers will only comply with the listing and certification requirements, the FDA's application of the statute will, under §706(d), be subject to the general administrative provisions on hearings and review in §701. Since the review authorized in §706(d) is directed at decisions approving or disapproving listing and certification and §§701(e) and (f) are limited to review of other specifically enumerated agency determinations, the contention is not that the statutory provisions afford a direct path to review of the general regulations on listing requirements; it is rather that they furnish an indirect but nevertheless sufficient one which the manufacturers ought to have taken. The proper course, defendants say, is for a manufacturer to petition for the listing of diluents and finished cosmetic products as color additives, while protesting against the need for doing so and conforming with the detailed requirements for filing information only to the extent he believes proper under the statute; such a petition could be accompanied by a request for exemption from batch certification,

again with appropriate protest and non-compliance with the requirement of factual data to support the application. Either the FDA would retreat from applying its announced interpretation of the statute and grant the petition and the request for exemption, or it would deny them in which event the road to a court of appeals would be open under §§701(e) and (f).

II.

The serious questions[6] are whether direct challenge of the Regulations by suit in a district court is impliedly barred by the availability of review of listing and certification denials in a court of appeals, and whether the controversy is appropriate for judicial determination prior to application of the Regulations in a particular factual situation.

We are not persuaded that by providing a procedure for review of certain administrative decisions under the Food and Drug Act in the courts of appeals, Congress meant to foreclose relief with respect to other agency action under the Administrative Procedure Act §10, 5 U. S. C. §1009, or the Declaratory Judgment Act, 28 U. S. C. §2201, in a case where this would otherwise be appropriate. The agency determinations specifically reviewable under §701(e) relate to such technical subjects as chemical properties of particular products and the formulation and application of safety standards for protecting public health; Congress naturally did not wish courts to consider such

[6] We need not discuss in the text the surprising contention that an action for a declaration that federal regulatory officers have acted in excess of their authority constitutes an unconsented suit against the United States. The contrary is clearly established by *Philadelphia Co.* v. *Stimson*, 223 U. S. 605, 619-20 (1912), see *Stark* v. *Wickard*, 321 U. S. 288, 290 (1944), and indeed follows inevitably from *Ex parte Young*, 209 U. S. 123 (1908); law officers of the Government ought not to take the time of busy judges or of opposing parties by advancing an argument so plainly foreclosed by Supreme Court decisions.

matters without the benefit of the agency's views after an evidentiary hearing before it. Section 701, however, also contemplated other less specialized administrative action by authorizing, in subsection (a), the making of regulations for the efficient enforcement of the statute, and it expressly declared in subsection (f) that the provision for review of certain orders in the courts of appeals was "in addition to and not in substitution for any other remedies provided by law." 21 U. S. C. §371(f)(6). The section as a whole does not indicate to us any congressional intent either to insulate administrative action not covered by subsection (e) from challenge as in excess of statutory authority, see *Stark* v. *Wickard,* 321 U. S. 288, 308-11 (1944); cf. *Cappadora* v. *Celebrezze,* 356 F. 2d 1, 5 (2 Cir. 1966), or to postpone immediate challenge to such action where awaiting the issuance of adjudicative orders subject to statutory review would provide less effective relief.[7] Insofar as *Abbott Labs.* v. *Celebrezze,* 352 F. 2d 286, 289 (3 Cir. 1965), cert. granted, intimates otherwise. we are unwilling to follow it.

The question whether a plaintiff may obtain judicial relief in cases like this has been variously phrased as

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[7] The legislative history of the 1938 Act suggests that Congress had no intention of limiting review of other action by adopting a special procedure for the enumerated determinations. The House Report, referring to the savings clause in §701(f)(6), stated:

> There is also saved as a method to review a regulation placed in effect by the Secretary whatever rights exist to initiate a historical proceeding in equity to enjoin the enforcement of the regulation, and whatever rights exist to initiate a declaratory judgment proceeding.
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> H. R. Rep. No. 2139, 75th Cong., 3d Sess., p. 11 (April 14, 1938).

The accompanying minority report, in endorsing the Secretary's challenge to the new review provisions as jeopardizing enforcement of the statute, indicated that the special procedure was understood to be an additional protection for industry and not an exclusive method of review of all actions for the benefit of the agency. H. R. Rep. 2139, Pt. 2 (April 21, 1938).

whether he has "standing" to challenge the administrative action as a person "suffering legal wrong" or "aggrieved" within the meaning of §10 of the APA, whether the dispute is an "actual controversy" within the Declaratory Judgment Act, or whether it is sufficiently "ripe" for resolution by the courts. See Jaffe, Judicial Control of Administrative Action 395-98 (1965). In fact, the critical issue is apt to be less a matter of standing or of actual controversy than of the advisability of reviewing an administrative rule prior to its application in a specific factual situation. The current healthy trend toward implementing agency policy by rule-making cuts both ways with respect to declaratory relief—increasing the need for this sort of assistance on the art of those subjected to such rules, see *Columbia Broadcasting Sys., Inc.* v. *United States,* 316 U. S. 407, 421 (1942), but also creating a danger that, unless the courts are circumspect, administration may be improperly halted, at least temporarily, before it has gotten the slightest start.[8] The problem is not to be solved, as the parties suggest, by applying some readily procurable litmus paper which will determine whether a controversy is "justiciable"; what is required, as in the case of challenge to the constitutionality of a statute, is a reasoned evaluation of "both the appropriateness of the issues for decision by courts and the hardship of denying judicial relief." *Joint Anti-Fascist Refugee Comm.* v. *McGrath,* 341 U. S. 123, 156 (1951) (Frankfurter, *J.*, concurring); see Jaffe, *supra,* at 396, 423.

The appropriateness of passing judgment on the validity of an administrative regulation prior to its application to

[8] The danger of unwarranted postponement of the effectiveness of agency action is augmented by the fact that a suit for declaratory relief must be brought in a district court, twice removed from the supreme tribunal, whereas adjudicative orders are generally reviewable either in courts of appeals or in specially constituted district courts from which appeal lies directly to the Supreme Court. Yet here too there is another side; a district court may be in a better position than a court of appeals to carry out fact finding, as Congress recognized in the Hobbs Act, 5 U. S. C. §1037(b).

particular facts depends on such factors as how far the rule represents the definitive position of the agency and the extent to which the challenge raises a clearcut legal issue susceptible of judicial solution without reference to fact variables arising in its implementation. Cf. *Northeast Airlines, Inc.* v. *CAB,* 345 F. 2d 662, 664 (1 Cir. 1965). Review might be considered premature where an agency rule had not received substantially as full consideration in its formulation as it would have in subsequent application, or where future experience would be likely to result in significant modifications as to its precision or scope. Judicial determination might also be deemed inappropriate where the controversy over the rule did not present a legal issue that a court was qualified to resolve without reference to factual determinations more effectively made by the agency familiar with day to day administration. See Jaffe, *supra,* at 406. In this case, however, the Regulations under attack were issued after a full hearing with notice and by their terms represent the definitive agency position on the reach of the statutory requirements for listing and certification of cosmetics, see *Columbia Broadcasting Sys., Inc.* v. *United States, supra,* 316 U. S. at 422; *United States* v. *Storer Broadcasting Co.,* 351 U. S. 192, 198 (1956); to the extent that they purport to apply premarketing requirements to broad categories like finished products and noncoloring ingredients and define the hair-dye exemption, they appear, *prima facie,* to be susceptible of reasoned comparison with the statutory mandate without inquiry into factual issues that ought to be first ventilated before the agency. Indeed, it is manifest that if the manufacturers adhere to their legal position, *pro forma* individual applications to the FDA for listing and certification would produce a record no more, and very likely less, illuminating than what the district court will develop at trial of this action in which the great bulk of the industry is represented and will be bound. The mere fact that the procedure which the defendants suggest would bring the issue

directly to a court of appeals without prior resort to a district court, while entitled to some weight, is not controlling. As indicated earlier, the statutory procedure for review of individual determinations in the courts of appeals was not intended as a means for challenging FDA rule-making of the usual sort; as shown by the authorities discussed below, the mere fact that pursuit of that course could produce a decision on legal issues similar to that here sought does not make its use mandatory.

With respect to the other relevant consideration, the degree of hardship warranting declaratory relief, although some older precedents suggest broadly that an administrative ruling is not reviewable until and unless it imposes an obligation or subjects the plaintiff to some civil or criminal liability, see, e.g., *United States* v. *Los Angeles & Salt Lake R.R.*, 273 U. S. 299, 309-10 (1927); *Shannahan* v. *United States*, 303 U. S. 596, 599 (1938), there has been a growing recognition that the timeliness of review depends on a broader concept of the substantiality of present or immediate harm. See 3 Davis, Administrative Law Treatise §2107 (1958). In *Columbia Broadcasting Sys., Inc.* v. *United States*, 316 U. S. 407, 417-21 (1942), the Supreme Court declared that though a particular rule does not of itself deny a license or directly impose sanctions, it may nevertheless be reviewable if it establishes a general standard of conduct which by its very promulgation demands conformity and poses, for the plaintiff or others with whom he must deal, the alternatives of compliance or severe penalties of forfeiture or disruption of business operations. In *Frozen Food Express* v. *United States*, 351 U. S. 40, 43-44 (1956), the Court recognized that an agency order generally announcing the scope of administrative regulation was subject to immediate frontal attack, although opportunities for later challenge were sure to come from a cease and desist order by the ICC, see *Eastern Texas Motor Lines* v. *Frozen Food Express*, 351 U. S. 49 (1956),

or suit for an injunction by the agency or competitors.[9] And in *United States* v. *Storer Broadcasting Co.*, 351 U. S. 192, 199-200 (1956), declaratory rules setting limits on the number of licenses to be granted for broadcasting stations under common ownership were held to be immediately reviewable because they operated "to control the business affairs" of the plaintiff and made it impossible to "cogently plan its present or future operations" so long as their validity remained undetermined; direct challenge to the regulations was permitted even though review might have been obtained by provoking an adverse administrative order, see 351 U. S. at 208 (dissenting opinion).[10] See also *Flemming* v. *Florida Citrus Exch.*, 358 U. S. 153, 168 (1958).

We see little profit in debating the point, much discussed by the parties, whether the Regulations are "interpretative" or "legislative." Although that issue would have to be faced if the FDA had failed to comply with the rule-

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[9] If it be said that the carrier was subject to liability for criminal penalties even before a cease and desist order or an injunction, the same is true here.

[10] In fact the FCC dismissed the plaintiff's application for an additional station on the basis of the new rules the very day they were adopted, 351 U. S. at 197, but review of the particular decision was not sought.

We recognize that in *Storer* review of the rule was in the Court of Appeals for the District of Columbia, the same tribunal to which Storer would have gone for review of the denial of an application; but the dissenters thought the rationale of the majority would support a suit for declaratory relief in a district court after the 60-day limitation for seeking review by the Court of Appeals had expired, 351 U. S. at 210 (dissenting opinion of Harlan, J.). A more important differentiating consideration may be that awaiting denial of a future application may not have afforded a broadcaster who had reached the ceiling so full an opportunity for challenge as might appear at first blush; if the application was a competitive one for a new license, the FCC might predicate denial on other grounds, and to negotiate a transfer of an existing license in the teeth of the multiple-ownership rules would be of dubious business practicability. However, this ground for distinguishing *Storer* would not apply to *Frozen Food Express*.

making procedures of §4 of the APA because of a claim on its part that the Regulations were merely "interpretative," the interpretative character of a regulation does not necessarily make it unripe for review; we perceive no reason why a rule whereby an agency subjects to regulation activities contended to be immune should be exempt from immediate review because it purports to interpret a statute although it would not be if made in the exercise, contended to be illegal, of a substantive rule-making power. See *Frozen Food Express* v. *United States, supra;* Jaffe, Judicial Control of Administrative Action 405-07 (1965); and 1 Davis, Administrative Law Treatise §5.03 (1965 Pocket Part), criticizing on this ground *American President Lines, Ltd.* v. *FMC,* 316 F. 2d 419 (D. C. Cir. 1963), on which defendants rely. Neither do we think anything is to be gained by an attempt at comprehensive review of the decisions; the many cases in this area are not truly reconcilable and the law has been moving in the direction of greater freedom of review, see Jaffe, *supra,* at 412-17 (which, *inter alia,* criticizes another decision relied on by defendant, *Helco Prods. Co.* v. *McNutt,* 137 F. 2d 681 (D. C. Cir. 1943)), and 3 Davis, Administrative Law Treatise §§21.06-21.08 (1958). We limit ourselves to the two recent Court of Appeals decisions which defendants most strongly urge upon us.

Danville Tobacco Ass'n v. *Freeman,* 351 F. 2d 832 (D. C. Cir. 1965), was a rather weak case for declaratory relief. The plaintiffs there were neither threatened with penalties nor, like those in *Frozen Food* and here, faced with the need of applying for licenses to permit continuation of an established business; moreover, there was no showing that the challenged regulation was in fact preventing expansion of their operations, since they had filed no applications and petitions by other applicants had been denied on grounds other than those attacked. Agreeing with the defendants that *Abbott Labs.* v. *Celebrezze,* 352 F. 2d 286 (3 Cir. 1965), cert. granted, is not distinguishable on any satisfying basis,

we must confess, with all respect, our inability to understand why the plaintiffs there should be required to violate the challenged FDA regulation in order to raise the same legal issue as to which the district court had granted declaratory relief. Insofar as the *Abbott* decision rested on a negative implication from the limited review provisions of the Food and Drug Act, we have already noted our inability to agree.

III.

In applying the general considerations thus developed to the precise issues here presented, we must bear in mind that this appeal is not from a declaratory judgment but from the denial of a motion to dismiss a complaint seeking one. The issue on such an appeal is not whether the grant of a declaratory judgment was in fact appropriate but whether it so clearly would not be that dismissal *in limine* was required.

As regards the counts of the complaint challenging the inclusion of finished products and color additives and the alleged restrictions of the hair-dye exemption, the appeal must fail. These Regulations appear to have an immediate impact on the industry, posing the unacceptable alternatives of complying or of incurring possible forfeitures and criminal liability, and calling into question long standing practices of premarketing testing and clearance. The issues framed by the counts of the complaint addressed to these Regulations appear sufficiently suitable for immediate judicial resolution and the threatened harm sufficiently great, that the district court properly declined to dismiss them. If the court should find that the issues are not susceptible of resolution without detailed factual evidence that ought to be first sifted by the agency, or that measures being taken by the FDA for the listing and exemption from certification of approved diluents have so reduced the hardship on the plaintiffs as to make declaratory relief inap-

propriate, it need not proceed to judgment. But, so far as we can now see, the sooner the industry's claims as to the coverage of the Act in these respects are determined, the better for everybody. As said in Jaffe, Judicial Review of Administrative Action 404 (1965), "The public has an interest in early implementation of policy; the regulated person has a legitimate interest whether to plan or not to plan his operation." Moreover, the party disappointed by court decision may wish to take the case to Congress.

The fourth count of the complaint, relating to agency inspection of formulae and processes, stands differently. Here the challenged regulation, §8.28(a)(4), does not of itself demand compliance at the expense of penalties. A manufacturer who refuses access to his trade secrets is not threatened with criminal liability or seizure; the regulation does not suggest that such refusal will be deemed a "prohibited act" under the statute, as it would be in the case of prescription drugs. It simply warns the industry that the Commissioner may—not that he inevitably will—consider a refusal to permit such inspection a sufficient cause for suspending certification. Moreover, the next paragraph, §8.28(b), says that upon receipt of notice of suspension, the person so notified may request a hearing upon the factual basis therefor. If after such hearing the Commissioner should adhere to his refusal to certify, review by a court of appeals would seem available under §§706(d) and 701(f); if not, an action could be brought in the district court.

In this instance the possibility of unlawful injury to the plaintiffs is, on its face, too remote for declaratory relief. No one can now say whether the Commissioner will ever make a demand for free access to color additive processes or formulae, whether any manufacturer will ever decline this, what the Commissioner would do if so refused, and what result a hearing would have. The fact that the Commissioner's proclamation of the possible consequences of refusal may induce manufacturers to be more compliant

than if he had kept silent until an episode calling for action arose is not a sufficient basis for declaratory relief. Moreover, it is impossible to see what declaration a court could properly make. No one could reasonably assert that circumstances warranting suspension of certification if a manufacturer refused to give the FDA information concerning processes or formulae could never arise; Congress' failure to empower the agency to compel an inspection of processes or formulae is not a mandate to grant certificates when the public cannot properly be protected otherwise. Review of this Regulation should be on a case by case basis and with a factual record to assist in determining whether access to secret processes and formulae is necessary and appropriate to performance of the task of effective premarketing clearance in a particular instance—at least in the absence of experience showing consistent abusive tactics.

The judgment with respect to Count 4 is reversed with instructions to grant the motion to dismiss; the judgment with respect to Counts 1, 2 and 3 is affirmed, with further proceedings to be promptly taken in the district court in accordance with this opinion.

APPENDIX B.

First Opinion of the United States District Court For the Southern District of New York.

Civil Action 63 Civ. 3349

(Filed November 16, 1964)

THE TOILET GOODS ASSOCIATION, INC., *et al.*,
Plaintiffs,

v.

ANTHONY J. CELEBREZZE, Secretary of Health, Education and Welfare, and George P. Larrick, Commissioner of Food and Drugs, Defendants.

TYLER, District Judge.

Forty individuals and companies manufacturing, distributing, and selling cosmetics in interstate commerce and an association of cosmetic manufacturers here seek a declaratory judgment [28 U.S.C. §2201] as to the validity of certain provisions of regulations promulgated by the Commissioner of the Food and Drug Administration (FDA). These regulations were issued pursuant to the 1960 Color Additives Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§301-381.[1] More specifically, plaintiffs contend that the challenged regulations exceed the authority vested in the FDA by the statute, as amended, and pray that the court declare the regulations null and void and enjoin their enforcement.

Essentially, the 1960 Amendments expand the Act's provisions for the pretesting of coal tar colors to require the pretesting of all color additives, irrespective of their derivation. To this end, the term "color additive" is

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[1] The Amendments were enacted on July 12, 1960.

defined as "a dye, pigment, or other substance" which, "when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable * * * of imparting color thereto." 21 U. S. C. §321(t)(1). The Amendments further state that color additives shall be deemed "unsafe" within the meaning of the Act unless they conform to regulations for the listing of additives and for "the certification, with safe diluents or without diluents, of batches of color additives." 21 U. S. C. §376.

To implement these Amendments, the Commissioner of the FDA issued the Color Additives Regulations, dated June 13, 1963.[2] 28 F. R. 6439, 21 C. F. R. §§8.1-8.6003. Those provisions of the regulations here challenged as in excess of the statutory authority on which they purport to be based are:

(a) provisions of Section 8.1(f) which, it is claimed, may have the effect of defining a color additive as including finished cosmetic products, and consequently, of requiring the pretesting of finished products;

(b) provisions of Sections 8.1(f) and (m) which define color additives as including all diluents and which, plaintiffs claim, may require the pretesting, listing and certification of all ingredients of cosmetics containing a color additive mixture;

(c) provisions of Sections 8.1(f) and (u) which are claimed to make nugatory the statutory exemption for hair dyes, 21 U. S. C. §361(a) and (e); and

(d) provisions of Section 8.28(a)(4) which plaintiffs contend is an unwarranted grant of access by FDA investigators to all processes and formulae involved in the manufacture of cosmetics.

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[2] Actually, 21 U. S. C. §371(a) vests in the Secretary of the Department of Health, Education and Welfare the authority to promulgate Food & Drug Act regulations. Defendants' memoranda explain that the responsibility for their actual promulgation was delegated to the Commissioner.

Appendix B.

Defendants have moved for an order dismissing the complaint, and, alternatively, for an order "striking certain portions of the complaint."[3]

I.

Defendants' principal contention on their motion to dismiss is that the complaint fails to state a case of actual controversy, as required by the Declaratory Judgment Act, 28 U. S. C. §2201, particularly because of the absence of any threatened or attempted enforcement of the regulations.

Although the Declaratory Judgment Act was never intended or construed to grant the federal courts license to render advisory opinions, threatened enforcement of a statute or administrative regulation is not a *sine qua non* for its review under the Act. See Borchard, Declaratory Judgments (2d ed., pp. 365-6). In *Columbia Broadcasting System, Inc.* v. *United States,* 316 U. S. 407, 417-418, 62 S. Ct. 1194, 1200, 86 L. Ed. 1563 (1942), FCC regulations provided that radio stations would have their licenses revoked if they entered into contracts with networks containing certain prohibited clauses. The court held the regulations to be reviewable because of their serious impact upon the radio network's ability to conduct its business and stated that, "If an administrative order has that effect it is reviewable and it does not cease to be so merely because it is not certain whether the Commission will institute proceedings to enforce the penalty incurred under its regulations for non-compliance."

Recently, in *Abbott Laboratories* v. *Celebrezze,* 228 F. Supp. 855 (D. Del. 1964), where drug manufacturers challenged FDA labeling regulations, Chief Judge Wright held, at page 861:

> "Plaintiffs may have judicial review of interpretive regulations upon their promulgation without

[3] Defendants, however, have not specified which portions they wish stricken.

> awaiting some ultimate enforcement. Frozen Food Express *v.* United States, 351 U. S. 40, 76 S. Ct. 569, 100 L. Ed. 910 (1956); Federal Trade Commission *v.* Nash-Finch Company, 110 U. S. App. D. C. 5, 288 F. 2d 407. They need not await an action which would only make the threat of harm more pressing."

Thus, while the threat of enforcement is often present in cases where the courts have taken jurisdiction and rendered a declaratory judgment on the validity of a challenged regulation or statute, the existence of such a threat merely serves as some evidence indicating the presence of an actual controversy and that the plaintiff stands to suffer "real, immediate and incalculable" harm. See concurring opinion of Mr. Justice Douglas, *Joint Anti-Fascist Refugee Committee* v. *McGrath*, 341 U. S. 123, 175, 71 S. Ct. 624, 95 L. Ed. 817 (1951).

In *Maryland Casualty Co.* v. *Pacific Coal & Oil Co.*, 312 U. S. 270, 273, 61 S. Ct. 510, 512, 85 L. Ed. 826 (1940), the Supreme Court said that, "Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."

More specifically, as to the reviewability of administrative rulings, Chief Justice Stone said in *Columbia Broadcasting System, Inc.* v. *United States, supra,* 316 U. S. at page 425, 62 S. Ct. at page 1204:

> "The ultimate test of reviewability is not to be found in an overrefined technique, but in the need of the review to protect from the irreparable injury threatened in the exceptional case by administrative rulings which attach legal consequences to action taken in advance of other hearings and adjudications that may follow, the results of which the regulations purport to control."

This being the test, I find it difficult and indeed inappropriate, at least under the circumstances here presented, to resolve the issue of reviewability upon the technical distinction, pressed by defendants, between legislative and interpretive regulations. Parenthetically, I should add that I read no federal authority to precisely support the defendants' argument that the regulations here involved are "interpretive" as opposed to "legislative" and thus do not "approach a degree of finality such as would warrant access to the Courts". (See page 59 *et seq.* of the government's principal brief.)[4]

In any event, for reasons to be discussed hereinafter, I conclude that in a substantial and practical business sense plaintiffs are threatened with irreparable injury by the obviously intended consequences of the challenged regulations, and that to resort to later piecemeal resolution of the controversy in the context of individual enforcement proceedings would be costly and inefficient, not only for the plaintiffs but as well for the public as represented by the defendants.

The regulations force manufacturers to choose between complying with them, at a cost that may prove to be prohibitive for some of the plaintiffs, or ignoring them at the risk of incurring the statutory penalties should the regulations later be held valid. And, as Chief Judge Wright recently observed in the *Abbott Laboratories* case, *supra*, 228 F. Supp. at 862: "The declaratory judgment procedure is specifically suited for the determination of controversies where the plaintiffs must either comply with a contested regulation or continue their present course of conduct at their peril."

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[4] In fairness to defendants, however, it must be said that some commentators and courts have discussed this distinction in theoretical terms. See Davis, Administrative Rules—Interpretative, Legislative and Retroactive, and cases therein cited. 57 Yale L. J. 919, 928-29 (1948).

Appendix B.

An affidavit submitted on behalf of one of the plaintiffs asserts that the cost of compliance to this plaintiff alone will be over $50,000,000. While this amount is immediately suspect,[5] there can be little doubt but that the added records-keeping and laboratory testing costs in themselves will be extremely burdensome for all of the plaintiffs.

Aside from such measurable out-of-pocket costs of compliance, it is not difficult to perceive that the impact of the regulations on plaintiffs' present methods of doing business will be substantial and will give rise almost certainly to potentially greater expenses. That the latter are "hidden expenses" in the sense that they are presently incalculable does not diminish their significance. For example, in the area of research alone, plaintiffs' affidavits show that the provisions of the regulations dealing with listing and with access to all formulae and processes will have an immediate adverse effect upon further research and development of new products. The situation here, incidentally, contrasts sharply with the facts of *Helco Products Co.* v. *McNutt*, 78 U. S. App. D. C. 71, 137 F. 2d 681, 149 A. L. R. 345 (1943), where the plaintiff sought a declaratory judgment on the validity of a simple advisory opinion of the FDA elicited in response to the plaintiff's inquiry whether or not its proposed business venture would violate the Food and Drug Act. Rather, we are dealing with a case that more closely parallels *Wallace* v. *Currin*, 95 F. 2d 856 (4th Cir. 1938), aff'd., 306 U. S. 1, 59 S. Ct. 379, 83 L. Ed. 441 (1939). The court in that case held that the plaintiffs, tobacco warehousemen, could challenge the 1955 Tobacco Inspection Act in a declaratory judgment suit because of the Act's substantial interference with their businesses, notwithstanding the fact that the cost of compliance for each warehouseman would only be $25 per marketing season.

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[5] The affiant apparently confused §8.50(c) of the regulations, which requires a *deposit* of $2,600 for each listing application, with §8.50(j), which establishes a *fee* of $250 "for services in listing a diluent" for use in color additive mixtures.

Appendix B.

Having established that a justiciable controversy exists, there are at least two compelling reasons for assuming jurisdiction and determining in this action the validity of the challenged regulations.

First, since a concern for consumer safety is ostensibly the principal motive underlying promulgation of the Color Additives Regulations, there is a strong public interest in an early determination of their validity. Four years have already elapsed since Congress enacted the statutory provisions which the regulations seek to implement. Any further delay in determining whether or not the cosmetic industry need comply with the regulations will only serve to further frustrate Congress' purpose of providing the consuming public with protection against potentially harmful color additives.

Second, this action provides an opportunity to examine all four challenged regulatory provisions together within the context of a single plenary proceeding. Since these four provisions are interrelated as elements of a common plan of governmental regulation, there is a distinct advantage in reviewing them together. Moreover, since the regulations raise complicated and technical issues which will require expert testimony to resolve—undoubtedly from many of the same witnesses—there is a practical advantage for the litigants as well as for the court in having this testimony brought forth in a single action rather than in four or more separate suits or enforcement proceedings.

II.

Since I conclude that there is a justiciable controversy presented and further that it would be improvident to decline jurisdiction on discretionary grounds, this would dispose of the dismissal motion were it not for the fact that defendants raise two further arguments for dismissal of the entire action and two other arguments for dismissal as to certain of the plaintiffs. All four issues so raised must be resolved against defendants, at least at this stage of the proceedings:

Appendix B.

(1) This is not an unconsented suit against the United States. Keeping in mind the distinction drawn in *Larson* v. *Domestic & Foreign Commerce Corp.*, 337 U. S. 682, 69 S. Ct. 1457, 93 L. Ed. 1628 (1949), the thrust of the claim here is not that the Commissioner wrongly exercised his delegated powers—which would be a claim against the sovereign—but that he acted in excess of his statutory authority and therefore outside the scope of his delegated powers. And, as the Supreme Court said in *Larson*, at 689, 69 S. Ct. at 1461, "where the officer's powers are limited by statute, his actions beyond those limitations are considered individual and not sovereign actions." See *Abbott Laboratories* v. *Celebrezze, supra; Philadelphia Company* v. *Stimson*, 223 U. S. 605, 32 S. Ct. 340, 56 L. Ed. 570 (1912); *Federal Trade Commission* v. *Nash-Finch Company*, 110 U. S. App. D. C. 5, 288 F. 2d 407 (1961).

(2) The Attorney General is not an indispensable party to this action. This was the conclusion in the *Abbott Laboratories* case where the court said 228 F. Supp. at page 862: "The decree sought here does not operate against the Attorney General except in a secondary fashion. He will not be forced to do anything no matter how the court decides."

(3) The Toilet Goods Association does have standing to sue. The members of the Association account for more than 90% of the annual sales of cosmetics in the United States. They are individually harmed and the Association, as a proper representative of the interests of its members, can challenge the regulations in that capacity. *National Motor Freight Traffic Association* v. *United States*, 372 U. S. 246, 83 S. Ct. 688, 9 L. Ed. 2d 709 (1963); *Abbott Laboratories* v. *Celebrezze, supra.*

(4) Venue, predicated upon 28 U. S. C. §1391(c), is proper as to each of the individually named plaintiffs. Although not all the Circuits agree, this Circuit has consistently held that 28 U. S. C. §1391(c) applies to plaintiff

and defendant corporations alike. *Freiday* v. *Cowdin*, 83 F. Supp. 516 (S. D. N. Y. 1949); *Southern Paperboard Corporation* v. *United States*, 127 F. Supp. 649 (S. D. N. Y. 1955); *Wear-Ever Aluminum Inc.* v. *Sipos*, 184 F. Supp. 364 (S. D. N. Y. 1960).

Accordingly, defendants' motion to dismiss is denied in all respects.

III.

Since the papers already submitted by the parties raise substantive issues outside this court's ordinary sphere of competence, it would be unwise to make a determination on the merits at this stage without the aid of "live", expert testimony.

To be sure, the essential questions presented in this action are ones of statutory interpretation; whatever competence the court and counsel may have in this area generally, however, can only be enhanced by a particular understanding, to be obtained with expert assistance, of the technical problems involved. Additionally, since professionally qualified representatives of both plaintiffs and defendants were present during the hearings and debates which preceded the passage of the 1960 Color Additives Amendments, it would be helpful to hear their testimony relative to legislative intent, which, presumably, they had an important role in shaping and assisting.

Plaintiffs' motion for summary judgment, therefore is denied.

IV.

Inasmuch as defendants have not specified what they wish to have stricken from the complaint, their motion to strike is denied.

Settle order accordingly.

APPENDIX C.

Second Opinion of the United States District Court for the Southern District of New York.

Civil Action 63 Civ. 3349

(Filed December 13, 1965)

The Toilet Goods Association, Inc., *et al.*,
Plaintiffs,

v.

Anthony J. Celebrezze, Secretary of Health, Education and Welfare, and George P. Larrick, Commissioner of Food and Drugs, Defendants.

Tyler, D. J.

Defendants (hereinafter collectively referred to as "FDA"), with the permission of this court, have made a renewed motion to dismiss the complaint and for summary judgment pursuant to F. R. C. P. 56 and 28 U. S. C. 2201 on the grounds that the complaint fails to set forth a justiciable controversy and that this is an unconsented suit against the United States. In the alternative, defendants have moved for an order pursuant to the provisions of 28 U. S. C. 1292(b) certifying the aforesaid issues for an interlocutory appeal.

By way of background, the principal impetus for this renewed motion stems from recent opinions filed by the United States Courts of Appeals for the Third Circuit in *Abbott Laboratories* v. *Celebrezze, et al.*, 352 F. 2d 286, decided November 1, 1965, and for the District of Columbia in *The Danville Tobacco Association et al.* v. *Freeman*, 351 F. 2d 832, decided September 30, 1965. Both decisions, in general terms, were rulings that the district courts should

have dismissed complaints for failure to state justiciable controversies where complainants were ostensibly challenging the meaning and validity of agency regulations. Thus, FDA here asserts that the facts of the present case are substantially analogous to those in *Abbott* and *Danville Tobacco*, and that, therefore, the decision of this court filed on November 17, 1964 and determining, among other things, that the present case presents a justiciable controversy in a context not involving an unconsented suit against the United States, should be reconsidered and overturned.

The parties amply briefed the issues upon this renewed motion, and oral argument were heard on December 6, 1965. On December 8, 1965, this court filed an order denying the renewed motion of FDA for dismissal but certifying the questions presented for an interlocutory appeal. This memorandum is designed to sketch the principal reasons for this court's refusal to disturb its original determination filed approximately one year ago.

No useful purpose can be served here in replowing the same ground covered in the opinion of this court reported at 235 F. Supp. 648. Essentially, I do not agree with FDA's arguments that *Abbott* and *Danville Tobacco* present facts and circumstances apposite to the case at bar.[1]

As already indicated in the earlier opinion of this court, FDA in the last analysis has consistently bottomed all of its arguments upon the technical proposition that the regulations here under attack are "interpretive" as opposed to "legislative".[2] This cornerstone contention of FDA, it seems to me, has several deficiencies. Preliminarily, it smacks of hypertechnicality; in the words of Chief Justice Stone, "the ultimate test of reviewability is not to be found

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[1] Indeed, *Danville Tobacco* seems to me so obviously inapposite as to warrant no detailed discussion whatsoever. I suspect that FDA in part would agree because its papers and oral argument were principally keyed to *Abbott*, with little or no detailed discussion of *Danville Tobacco*.

[2] See discussion in 57 Yale L. J. 919, 928-9 (1948).

in an over-refined technique . . .". *Columbia Broadcasting System, Inc.* v. *United States*, 316 U. S. 407, 425 (1942). More significant, this court has already found upon the allegations of the complaint in this case that FDA has promulgated final regulations pursuant to the Color Additives Amendments of 1960 enacted by Congress as part of the Food, Drug and Cosmetics Act (74 Stat. 397, Public Law 86-618, 86th Cong., 2d Session, 21 U. S. C. 321 (+) and 376) (hereinafter the "Act"); that there is raised by the parties a substantial issue as to whether or not four of these final regulations significantly exceed the legislative mandate of the 1960 Amendments; and that irreparable harm would attach to plaintiffs unless these issues are resolved in this declaratory judgment action prior to piecemeal administrative litigation upon individual license applications. It is in the light of these findings that I reach my opinion that *Abbott*, and, of course, *Danville Tobacco*, are distinguishable from this case.

Granting *arguendo* that *Abbott Laboratories* is generally more similar to the present controversy, it must be emphasized that there the applicable statutory provision[3] merely required that with respect to prescription drugs, the established or generic drug name be printed "prominently" on the label in type half as large as any brand or proprietary name. Presumably, this "prominently" requirement could be satisfied in a number of ways such as by means of a special label in large type-face, or by printing the generic name in bold red letters and the like. In its pertinent regulations, FDA in effect provided that the generic name must be shown "prominently" not only on labels but "each time" the trade name is used for any purpose, whether it be advertising, labelling or whatever. Perhaps understandably under these circumstances, the Court of Appeals ruled that the issue presented was one of interpretation of the regulations in question and, as such, not cognizable by the district court.

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[3] Section 502(e)(1)(B) of the Act.

But the situation in this case is significantly different. Here the plaintiff contends that: (1) the 1960 Color Additive Amendments require merely pretesting, listing and certification for dyes, pigments and other color ingredients; (2) they do not change the statutory exemption for hair dyes; and (3) they do not grant FDA access to industry formulae for cosmetic products. But plaintiffs also allege that FDA has issued regulations, purportedly under the authority of the Color Additive Amendments, which would: (1) require pretesting, listing and certification for finished cosmetic products, including hair dyes, and, as well, for the non-color ingredients of finished cosmetics; (2) change and limit the statutory exemption for hair dyes; and (3) grant FDA inspectors access to cosmetic formulae. In short, the complaint contains significant allegations of administrative regulations which rather markedly depart from what preliminarily appears to be the plain legislative authority conferred by Congress in the 1960 Color Additives Amendments.[4] Thus it is that in my opinion this case presents a different issue of "reviewability" or "justiciability" than that before the court in *Abbott Laboratories*.[5] Upon the complaint allegations, this is not necessarily a case where, as FDA is prone to argue, the parties are simply bickering as to how the regulations are to be interpreted and applied. Rather, on the face of the pleadings, this is a case involving allegations of serious and significant excesses by an executive agency, through the device of final regulations, beyond the powers conferred by Congress upon the agency in the 1960 Amendments. Whether or not these claims are true presents, in my view, a justiciable controversy which is ripe for determination by a district court under the Declaratory Judgment Act.

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[4] For other possible distinguishing factors, see discussion of this court at 235 F. Supp. at pages 651-2.

[5] Moreover, even if it be said that this case is not distinguishable from *Abbott*, then I would disagree with the reasoning and ultimate result to date of the latter case.

In reaching the latter conclusion, I am not unaware of another argument of FDA which, though not novel, takes on special focus by virtue of certain discussion of the Court of Appeals in *Abbott Laboratories*. FDA urges as a principal argument against reviewability here that Congress has provided another and more efficacious remedy for aggrieved industry members. In substance, this is the remedy of judicial review by a Court of Appeals from individual orders of the FDA upon applications for licenses for cosmetics, all as set forth in subsection (f)(1-5) of Section 701 of the Act. Apparently, FDA obtains comfort from certain statements concerning this statutory method of review by the Court of Appeals at pages 8 and 9 of its slip opinion in *Abbott Laboratories*. But, as I see it, such is cold comfort indeed in view of the fact that the Court of Appeals in *Abbott Laboratories* at the threshold had determined that they were concerned with an interpretative as opposed to "legislative" regulations such as are alleged in the case at bar. Moreover, subsection (f)(6) of Section 701 of the Act underscores the Congressional intention that the special review of license proceedings by the Courts of Appeals "shall be in addition to and not in substitution for any other remedies provided by law". Finally, it is scarcely to be thought that judicial review limited to the traditional and narrow scope of whether or not the Commissioner's findings are supported by adequate evidence can supplant the other and broader form of remedy or review available under the Declaratory Judgment Act.

A brief, final paragraph may be in order respecting that part of this court's December 8, 1965 order certifying the questions pursuant to 28 U. S. C. 1292(b). Aside and apart from the circumstance that plaintiffs have agreed to the FDA's request for certification, it is clear from a review of the general case law in this field that, notwithstanding my firmly held views on the issues here of justiciability and whether or not this is an unconsented suit against the sovereign, there is ample room for difference of opinion.

Appendix C.

Further to bespeak the obvious, a different view than mine would quickly terminate this litigation, which, though only commenced last year due to doubtless necessary delays in the regulation making process, involves subject matters passed upon by the Congress five years ago. Even if the reviewing court were to agree that this court has properly taken jurisdiction, it must be borne in mind that this case was ready to proceed to trial on December 6, 1965, the day when this renewed motion was argued—*i.e.* in the event of an unsuccessful interlocutory appeal, this case presumably can be resolved on the merits without undue additional delay.

December 10, 1965.

/s/ H. R. Tyler, Jr.
U. S. D. J.

APPENDIX D

Judgment of the Court of Appeals

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT.

At a Stated Term of the United States Court of Appeals, in and for the Second Circuit, held at the United States Courthouse in the City of New York, on the thirteenth day of April one thousand nine hundred and sixty-six.

Present:

HON. STERRY R. WATERMAN,
HON. LEONARD P. MOORE,
HON. HENRY J. FRIENDLY,
Circuit Judges.

THE TOILET GOODS ASSOCIATION, INC., *et al.*,
Plaintiffs-Appellees,

v.

ANTHONY J. CELEBREZZE, Secretary of Health, Education and Welfare, and GEORGE P. LARRICK, Commissioner of Food and Drugs,
Defendants-Appellants.

Appeal from the United States District Court for the Southern District of New York.

This cause came on to be heard on the transcript of record from the United States District Court for the Southern District of New York, and was argued by counsel.

Appendix D.

ON CONSIDERATION WHEREOF, it is now hereby ordered, adjudged, and decreed that the order of said District Court be and it hereby is affirmed as to the First, Second and Third Counts of the complaint.

It is further ordered that the order of said District Court be and it hereby is reversed as to the Fourth Count of the complaint with instructions to grant the motion to dismiss in accordance with the opinion of this court.

A. DANIEL FUSARO
Clerk

APPENDIX E

Federal Food, Drug, and Cosmetic Act, as Amended

Section 201(t), 52 Stat. 1040 (1938), as amended by Section 101(c) of the Color Additive Amendments of 1960, 74 Stat. 397 (1960), 21 U.S.C. §321(t):

"CHAPTER II—DEFINITIONS

"SEC. 201. For the purposes of this Act—

• • • • • •

"(t) (1) The term 'color additive' means a material which—

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

"(2) The term 'color' includes black, white, and intermediate grays.

"(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of

produce of the soil and thereby affecting its color, whether before or after harvest."

Section 704(a), 52 Stat. 1057 (1938), as amended by Section 201 of the Drug Amendments of 1962, 76 Stat. 792 (1962), 21 U.S.C. §374(a):

"FACTORY INSPECTION

"SEC. 704 [374]. (a) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing

on violation of this Act. No inspection authorized for prescription drugs by the preceding sentence shall extend to (A) financial data, (B) sales data other than shipment data, (C) pricing data, (D) personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and (E) research data (other than data, relating to new drugs and antibiotic drugs, subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (j) or section 507 (d) or (g) of this Act, and data, relating to other drugs, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) of this Act). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

APPENDIX F

Regulations of the Food and Drug Administration, 21 CFR Part 8

"Subpart A—Definitions and Procedural and Interpretative Regulations

"§ 8.1 Definitions and interpretations.

* * * *

"(f) A 'color additive' is any material, not exempted under section 201(t) of the act, that is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source and that, when added or applied to a food, drug, or cosmetic or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting a color thereto. This includes all diluents. Substances capable of imparting a color to a container for foods, drugs, or cosmetics are not color additives unless the customary or reasonably foreseeable handling or use of the container may reasonably be expected to result in the color being transmitted to the contents of the package or any part thereof. Food ingredients such as cherries, green or red peppers, cholocate, and orange juice which contribute their own natural color when mixed with other foods are not regarded as 'color additives'; but where a food substance such as beet juice is deliberately used as a color, as in pink lemonade, it is a 'color additive.' Food ingredients as authorized by a definition and standard of identity prescribed by regulations pursuant to section 401 of the act are 'color additives,' where the ingredients are specifically designated in the definitions and standards of identity as permitted for use for coloring purposes. An ingredient of an animal feed whose intended function is to impart, through the biological

processes of the animal, a color to the meat, milk, or eggs of the animal is a color additive and is not exempt from the requirements of the statute. This definition shall apply whether or not such ingredient has nutritive or other functions in addition to the property of imparting color. A substance that, when applied to the human body results in coloring, is a 'color additive,' unless the function of coloring is purely incidental to its intended use, such as in the case of deodorants. Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body are 'color additives.' An ingested drug the intended function of which is to impart color to the human body is a 'color additive.' For the purposes of this part, the term 'color' includes black, white, and intermediate grays, but substances including migrants from packaging materials which do not contribute any color apparent to the naked eye are not 'color additives.' "

§ 8.28 Authority to refuse certifiation service.

"(a) When it appears to the Commissioner that a person has:

(1) Obtained, or attempted to obtain, a certificate through fraud or misrepresentation of a material fact.

(2) Falsified the records required to be kept by §8.26; or

(3) Failed to keep such records, or to make them available, or to accord full opportunity to make inventory of stocks on hand or otherwise to check the correctness of such records, as required by §8.26; or

(4) Refuse to permit duly authorized employees of the Food and Drug Administration free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived;

he may immediately suspend certification service to such person and may continue such suspension until adequate corrective action has been taken.

"(b) Upon receipt of the notice of suspension of service, the person so notified may request a hearing upon the factual basis for the suspension. The procedure at the hearing shall conform as nearly as possible to the procedure described in §§130.14-130.26 of this chapter."

(5776)

APPENDIX G.

The Proposed Factory Inspection Provisions of H. R. 11581

"[H.R. 11581, 87th Cong., 2d sess.]

"A BILL To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety, efficacy, and reliability of drugs, authorize standardization of drug names, establish special controls for barbiturate and stimulant drugs, and clarify and strengthen existing inspection authority with respect to any articles subject to the Act; and to amend related laws

"*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled*, That this Act, divided into titles and sections according to the following table of contents, may be cited as the 'Drugs and Factory Inspection Amendment of 1962'.

• • • • • •

"TITLE II—CLARIFICATION AND STRENGTHENING OF FACTORY INSPECTION AUTHORITY

FACTORY INSPECTION

"SEC. 201. (a) The first sentence of subsection (a) of section 704 of the Federal Food, Drug, and Cosmetic Act is amended to read as follows: 'For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any consulting laboratory, or to enter any vehicle being used to transport or hold

such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, consulting laboratory, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein, and all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether articles which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violations or potential violations of this Act'."

APPENDIX H

The Proposed Factory Inspection Provisions of H. R. 6788

"88th Congress 1st Session

H. R. 6788

"A BILL To protect the public health by amending the Federal Food, Drug and Cosmetic Act to extend and clarify existing inspection and investigative powers, require a premarketing showing of the safety of cosmetics, assure the safety, efficacy, and reliability of therapeutic, diagnostic, and prosthetic devices, inprove the statutory coordination between that Act and the biological-drug provisions of the Public Health Service Act, provide for cautionary labeling of articles where needed to prevent accidental injury, and for other purposes.

"*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled*, That this Act, divided into titles and sections according to the following table of contents, may be cited as the 'Food, Drug, and Cosmetic Act Amendments of 1963.'

• • • • • •

"TITLE I—INSPECTION AND PRODUCTION OF EVIDENCE

"Extension of Prescription Drug Inspection Authority to Other Drugs, Food, Cosmetics, and Devices

"Sec. 101. (a) Section 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 374(a)) is amended by—

• • • • • •

"(6) striking out in the second sentence all beginning with the words 'In the case of any factory'

down through and including the words 'shall extend to', and thus combining such sentence with the first sentence;

"(7) striking out in the same sentence the subsequent words 'prescription drugs' and inserting in lieu thereof the word 'articles';"

APPENDIX I.

Secretary's Letter to the Speaker Transmitting H. R. 6788.

Department of
HEALTH, EDUCATION, AND WELFARE

May 29, 1963

Dear Mr. Speaker:

There is enclosed herewith a draft bill with the short title, "Food, Drug, and Cosmetic Act Amendments of 1963" which is designed to strengthen consumer protection.

This bill would carry out certain recommendations made by President Kennedy in his Consumer Protection Message of March 15, 1962, his Health Message of February 7, 1963, and his Message on Elderly Citizens of February 21, 1963, and make certain other improvements in food and drug laws.

1. *Extension and clarification of inspection authority under the Federal Food, Drug, and Cosmetic Act to determine whether food, nonprescription drugs, cosmetics, and therapeutic devices are being manufactured and marketed in accordance with the law.*

On October 10, 1962, the Drug Amendments of 1962 were enacted as P. L. 87-781. Section 201 of this law provided for strengthened inspection authority with respect to prescription drugs. With certain exceptions, the amendment permits inspection of prescription drug establishments (and makes clear our authority to make inspection of independent consulting laboratories for such establishments) to encompass access to all things (including records, files, papers, processes, controls, and facilities) which have a bearing on violation of the law with respect to such drugs.

Similar authority is needed with respect to other products covered by the Food, Drug, and Cosmetic Act. Manufacturers of such products can, and a substantial number do, refuse to allow the Food and Drug Administration to make sufficient inspection of their manufacturing operations and related records to permit a sound judgment as to the legality of their operations. In the 15-month period ending March 31, 1963, 436 food firms refused to permit Food and Drug Administration inspectors to make one or more phases of inspection needed for a true evaluation of the purity and safety of the firm's output. For example, the Food and Drug Administration is hampered in determining whether poisonous ingredients are present in food and cosmetics when it is denied access to formulas. Three hundred and twenty-two of the food firms referred to above refused, for example, to furnish qualitative or quantitative formulas. And with respect to proprietary drugs, the quality control requirements for drug manufacture enacted last year would be difficult, if not impossible, to enforce unless we have inspection authority of the same scope as for prescription drugs.

Authority is also needed to make complete inspections of retail pharmacies. At present retail pharmacies are exempt from the recently broadened inspection provisions (with respect to records, etc.) relating to other establishments handling prescription drugs. Thus, the Food and Drug Administration cannot make needed investigations of the receipt and dispensing of dangerously adulterated or misbranded drugs, such as decomposed, over-age life-saving drugs, or certain other critical inspections in the retail drug store. The Food and Drug Administration should be able to review prescription files when stocks of dangerous prescription drugs are being removed from the market and when investigations are being made of druggists suspected of selling potent prescription-only drugs without prescriptions. It should also be able to inspect all other kinds of relevant pharmacy records, other than prescription files.

The enclosed bill would, therefore, extend the inspection authority presently applicable only to prescription drugs to all other products covered by the Food, Drug, and Cosmetic Act, permit the review of drugstore prescription files when the inspector has reason to believe that the pharmacy has dispensed prescription drugs intended for human use in violation of the Act's provisions governing the dispensing of such drugs, or when the inspector is tracing the distribution of dangerously adulterated drugs or devices, or of a new drug or device in violation of the new-drug section's requirements, and permit the inspection of nonprescription records of pharmacies.

* * * * * * *

Sincerely,

ANTHONY J. CELEBREZZE,
Secretary.